

REMARKS / ARGUMENTS

The action by the Examiner in this application, together with the references cited, has been given careful consideration. Following such consideration, claims 1, 9 and 10 have been amended, claims 5, 7 and 8 were canceled, and claims 2-4 and 11-14 remain unchanged. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

As the Examiner well knows, the present invention is directed to a sterilization or decontamination system for decontaminating a region or space.

Most gaseous and vapor sterilization/decontamination systems rely on maintaining certain process parameters in order to achieve a target sterility or decontamination assurance level. For hydrogen peroxide vapor/sterilization/decontamination systems, those parameters include establishing and maintaining a desired concentration of hydrogen peroxide in a room or chamber. Conventional vaporized hydrogen peroxide (VHP) sterilization systems for decontaminating large rooms or isolators are generally closed-loop systems that contain a destroyer, a blower, a vapor generator and a dryer. In such system, a vaporized sterilant is continuously conveyed through a room or chamber. Typically, a sterilant exiting the room or chamber is directed to a destroyer to break down the vaporized hydrogen peroxide into water and oxygen. During a decontamination cycle, the region or chamber to be decontaminated is first dried to a low humidity level using a desiccant dryer. After the drying phase is complete, a "conditioning phase" is run, wherein sterilant is injected into the region or chamber. A problem with conventional closed-loop systems is that during the decontamination phase, vaporized sterilant exiting the region or chamber is destroyed because the destroyer and dryer are part of the closed-loop system. In other words, the vaporized sterilant is destroyed as it exits the region or chamber to be decontaminated. As a result, the vaporizer must continuously introduce new sterilant into the chamber or region. This method of operation limits the rate at which the concentration of sterilant can be increased in the room or region during the conditioning phase. The present invention addresses this problem, and provides a decontamination system that

increases the rate at which the concentration of the sterilant can be increased within a region or chamber.

The claimed decontamination system includes a closed loop circulation system that defines a first flow path along which a carrier gas and a decontaminant are conveyed. According to the present invention, a generator for generating a vaporized decontaminant, such as vaporized hydrogen peroxide is disposed along a first fluid flow path. A blower is also disposed along the first fluid flow path for conveying the carrier gas along the path. Likewise, a destroyer is disposed along a fluid flow path to destroy the vaporized decontaminant.

Stated another way, the vapor generator, the destroyer and the blower are all disposed along the first fluid flow path. In accordance with one aspect of the present invention, a bypass conduit is connected to the closed-loop system to isolate, or bypass a portion of the first fluid flow path. Specifically, the bypass conduit bypasses that portion of the first fluid flow path that includes the destroyer. In this respect, the bypass conduit essentially forms a second fluid flow path comprised of the remaining portion of the first fluid flow path and the bypass conduit. In other words, the second fluid flow path includes the generator and blower, but does not include the destroyer therein. A valve associated with the bypass conduit and the circulation system is used to control the direction of flow of the carrier gas, i.e., either along the first fluid flow path including the destroyer or along the second fluid flow path wherein the destroyer is bypassed.

In response to the Examiner's rejections, claims 1 and 10 have been amended to indicate that the generator and the destroyer are disposed along the "first fluid path" of the closed-loop circulating system. The claims have been further amended to indicate that the bypass conduit bypasses "a portion of the first fluid flow path." The claims have further been amended to define a valve associated with the bypass conduit. The valve has a first position and a second position. In the first position, a carrier gas is directed along the first fluid flow path including that portion of the first fluid flow path having the destroyer therein. In the second position, fluid flow is directed along the bypass conduit thereby bypassing that portion of the fluid flow path having the destroyer therein.

It is respectfully submitted that none of the cited references, alone or together, teaches, suggests or shows a vapor decontamination system having a closed-loop circulation system that

defines a first fluid flow path that includes both a vapor generator and a destroyer, and further includes a bypass conduit that defines a second flow path, which bypass conduit bypasses that portion of the first fluid flow path containing the destroyer.

The claims stand rejected under 35 U.S.C. Section 103(a) as being unpatentable over PCT International Publication No. WO 01/21223 A1 to Martin et al. in view of U.S. Patent No. 5,906,794 to Childers. As previously argued, the Martin et al. reference discloses an apparatus for sterilizing an enclosure that includes a closed-loop system that includes two (2) "parallel branches," designated 17 and 18 in FIG. 1 of the Martin et al. reference. As shown in FIG. 1 of the Martin et al. reference, the generator, identified as an evaporator 26, is disposed in branch 18 whereas the destroyer, identified as deactivate sterilant 22, is disclosed in branch 17. In this respect, the generator and destroyer of the Martin et al. reference are disposed parallel to each other, and are not disposed along the same fluid flow path, as defined in claims 1 and 10. In other words, the Martin et al. reference does disclose a bypass line around a destroyer, but it does not disclose a bypass line around a destroyer in a system wherein the generator and destroyer are disposed along the same fluid flow path. By providing the destroyer and generator along the same fluid flow path, redundant components can be eliminated from the system thereby simplifying the overall system and reducing the cost thereof. In this respect, the Examiner's attention is drawn to FIG. 1 of the Martin et al. reference that shows that each branch 17, 18 includes a fan (i.e., blower), a non-return valve, and a heater. In contrast, Applicant's system includes a single heater, a single fan and a single valve to bypass the destroyer. Applicant's arrangement, i.e., providing the blower, generator and destroyer along a single flow path and providing a bypass conduit that merely bypasses that portion of the first fluid flow path containing the destroyer, greatly simplifies the overall system, and eliminates the redundant features and components set forth in the Martin et al. reference.

With respect to the '794 patent to Childers, this reference discloses a closed-loop flow through vapor phase decontamination system having a single generator and destroyer disposed along a first path. In the '794 reference, a bypass arrangement is provided around the dryer for the purpose of maintaining a predetermined saturation of the decontaminant vapor in the chamber. The Examiner takes the position that "both references teach the recognized importance

of maintaining the sterilant vapor concentration at an optimal level during sterilization flow.” Applicant respectfully submits that the present invention is not directed to “maintaining” an “optimal” operating level. The present invention attempts to maximize the rate of increase of the concentration of sterilant in the chamber during a conditioning phase. It does so by not destroying the sterilant that exits the chamber when the destroyer is bypassed. In other words, by bypassing the destroyer, none of the vapor decontaminant generated by the generator is broken down as it exits the chamber, and therefore, a more rapid build-up can occur during the conditioning phase when it is desirable to bring the concentration of sterilant in the chamber quickly to a desired operating level. Thereafter, flow is re-directed along a first fluid flow path through the destroyer wherein operating features of the system can be used to attempt to “maintain” the optimal level of sterilant during a sterilization cycle.

The Childers ‘794 patent is clearly directed to a structure for monitoring the temperature, relative humidity and decontaminant vapor concentration in a chamber and attempts to control such parameters by bypassing a dryer. The Martin et al. reference attempts to control the operating parameters of the system by using two (2) parallel branch systems, each having its own blower, non-return valve and heater, and trying to balance the generation and destruction of a vapor sterilant in closed-loop system. In contrast, Applicant’s system has been designed to rapidly increase the concentration level of a sterilant in the chamber by completely bypassing a destroyer in a closed-loop system wherein the destroyer, generator and blower are arranged along the flow path of a closed-loop system.

In response to Applicant’s arguments, the Examiner states that “the destroyer of Martin [can] be configured in a by-pass loop as taught in Childers.” Applicant respectfully submits that there would be no motivation to bypass the destroyer in Martin et al. based upon the teachings of Childers. In this respect, the second parallel branch 18 of the Martin et al. reference already provides a bypass to the destroyer 22 in the first parallel branch 17 of the Martin et al. reference. Putting a bypass around the destroyer 22 of Martin et al. would seem to have no purpose in view of the two (2) parallel branch arrangements of the Martin et al. reference.

For the foregoing reasons, Applicant respectfully submits that the cited references, alone or together, do not teach, suggest or show a closed-loop sterilant system having a blower,

destroyer and generator disposed along a first flow path defined by the closed-loop system, and a bypass that bypasses that portion of the closed-loop system containing the destroyer. Such a structure allows for rapid build up of vaporized hydrogen peroxide during a conditioning phase, and allows for normal operation during other phases of the sterilization cycle. It likewise provides a system that does not require multiple components, such as shown in the Martin et al. reference.

For the foregoing reasons, Applicant respectfully submits that the claims in their present form are distinguishable from the cited reference, and favorable action is therefore respectfully requested.

Respectfully submitted,

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